

REMARKS

Claims 99-104 and 107-115 are pending after entry of this paper. Claims 99-104 have been rejected. Claims 107-115 have been withdrawn and claims 1-98, 105, and 106 have been cancelled without prejudice. Applicants reserve the right to pursue withdrawn and cancelled claims in a divisional or continuing application.

Claims 99-101 and 103 have been amended.

Support may be found throughout the instant specification. (See, e.g., Example 4, pages 92-99; pages 72-78 of the published PCT application WO 2004/047863; and pages 41-42 of the instant specification.)

No new matter has been introduced by these amendments. Reconsideration and withdrawal of the pending rejections in view of the above claim amendments and below remarks are respectfully requested.

Priority

Applicants submit that the instant application should be granted a priority date of at least November 21, 2003. The instant application is a national phase application under 35 U.S.C. §371 of International Application No. PCT/EP2003/013091. The applicants have claimed the benefit of the PCT application in their oath/declaration filed on May 20, 2005, and the applicants assert that the instant application, as well as the international application provide enabling disclosures of the instant claims.

The Examiner alleges that Application No. PCT/EP2003/013091 was not published in English and thus allegedly does not meet the requirements of PCT article 11 (See Office Action of June 27, 2007, page 3). The applicants respectfully disagree

with the Examiner's contentions. The applicants respectfully direct the Examiner's attention to 35 U.S.C. §365, 35 U.S.C. §371, and PCT Article 11, which do not require that the international application be submitted in English, but require that the PCT application be filed "in the prescribed language" (See PCT Article 11(1)(ii)). The international application was filed in the European Patent Office, which allows applications to be filed in German. In accordance with 35 U.S.C. §371(c)(2), applicants have submitted to the PTO "a translation into the English language of the international application" at the time of the National Stage entry, on May 20, 2005.

Thus, applicants respectfully request that the instant application be granted a priority date of November 21, 2003. Applicants amended the instant specification on May 20, 2005, to add a new paragraph to include the priority information.

Response to 35 U.S.C. §112 Rejection, First Paragraph- Enablement

Claims 99-104 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. Applicants respectfully disagree. However, in order to expedite prosecution without disclaimer of or prejudice to the subject matter recited in the instant application, applicants have amended the claims. Specifically, claims 99-101 have been amended to disclose a methodology of diagnosing stomach, lung, pancreatic, or esophageal cancers. No new matter has been introduced with this amendment. Support may be found throughout the instant specification, claims, and figures, for example, on page 97, line 36 – page 98, line 30, and in Figures 29 – 31 of the application as filed, as well as Example 4 ("Beispiel 4" on

pages 72 – 78) and Figures 29 – 31 of priority PCT Application No. PCT/EP2003/013091 (published as: WO 2004/047863).

The Examiner has admitted that, “the specification is enabling for diagnosing stomach cancers and lung cancers by detecting the expression of Claudin-18A2 protein...” (See, page 4 of the Office Action dated June 27, 2007). The applicants agree. Additionally, the applicants assert that diagnosing pancreatic and/or esophageal cancer is also enabled by the instant specification because the methodology for diagnosing these cancers would be the same as the methodology used for diagnosing stomach and lung cancers. Table 3A of the application as filed (also, “Tabelle 3A” on p. 74 of the published PCT application WO 2004/047863) shows that Claudin-18A2 is overexpressed in pancreatic and esophageal cancers, similar to stomach and lung cancers. Thus, applicants assert that diagnosing pancreatic and esophageal cancers is also enabled by the instant specification and claims as filed.

The Examiner is of the opinion that Table 3 of the instant specification is drawn only to mRNA expression in the pancreas and esophageal cancer and that there is no predictable correlation between mRNA levels and protein levels (Advisory Action, page 2, paragraph 2). Applicants respectfully disagree with the Examiner’s contention. Applicants respectfully direct the Examiner’s attention to the instant specification which shows that increased mRNA expression of lung cancer (See, Table 3 and Figures 29-31) also correlates with increased Claudin-18A2 protein expression (See, page 98, lines 25 – 29, and Figures 29-31 of the specification as filed). Applicants assert that a person of ordinary skill in the art would understand that the correlation between the increase in Claudin-18A2 mRNA expression with the increase in Claudin-18A2 protein expression

would be expected in all cancer types that overexpress Claudin-18A2 mRNA (i.e., the correlation would not be unique to lung cancer alone). Thus, the applicants assert that diagnosing pancreatic and esophageal cancers is also enabled by the instant specification and claims as filed because there is a correlation between increased mRNA expression and increased protein expression of Claudin-18A2 in pancreatic and esophageal cancers.

Therefore, the applicants assert that the claims contain subject matter which is described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants respectfully request reconsideration and withdrawal of the enablement rejection under 35 U.S.C. §112, first paragraph to claims 99-104 in view of the above-mentioned claim amendments.

Response to 35 U.S.C. §112 Rejection, First Paragraph- Written Description

Claims 99-104 have been rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Examiner contends that these claims lack an adequate written description because the claims read on fragments of the claimed polypeptides, and thereby diagnosing cancer based on those fragments. Applicants respectfully disagree. However, in order to expedite prosecution without disclaimer of or prejudice to the subject matter recited in the instant application, applicants have amended the claims for clarity. Specifically applicants have amended independent claim 99 to be directed to detecting the

expression of a tumor-associated antigen in a biological sample, where the tumor-associated antigen is either the polypeptide SEQ ID NO:16 or the polypeptide encoded by the nucleic acid sequence SEQ ID NO:7. Applicants assert that the amended claims are directed to the entire polypeptide sequences of the claimed polypeptides.

Applicants assert that the instant specification provides an adequate written description so that one skilled in the art would understand that the applicants had possession of the claimed invention at the time that the instant application was filed. Thus, applicants respectfully request reconsideration and withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph to claims 99-104 in view of the above-mentioned claim amendments.

Response to Claim Objections

Claim 103 has been objected to because there is a period after the word "a" before the end of the sentence. This claim has been amended to remedy the informality. Applicants respectfully request reconsideration and withdrawal of this objection.

Dependent Claims

Applicants have not independently addressed all of the rejections of the dependent claims. Applicants submit that for at least similar reasons as to why independent claim 99 from which all of the dependent claims 100-104 depend are believed allowable as discussed *supra*, the dependent claims are also allowable. However, applicants reserve the right to address any individual rejections of the dependent claims and present independent bases for allowance for the dependent claims should such be necessary or appropriate.

Thus, applicants respectfully submit that the invention as recited in the claims as presented herein is allowable and respectfully request that the respective rejections be withdrawn.

CONCLUSION

Based on the foregoing amendments and remarks, the applicants respectfully request reconsideration and withdrawal of the pending rejections and allowance of this application. The applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendment and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided. Favorable action by the Examiner is earnestly solicited.